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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO.

**EXAMINER**

ART UNIT	PAPER NUMBER
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DATE MAILED:

6

Please find below and/or attached an Office communication concerning this application or proceeding.

## **Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/601,371	Seya et al.
	Examiner	Art Unit
	Sarada C Prasad	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 18 December 2000.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claims 1-10 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- 15) Notice of References Cited (PTO-892)
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 19) Notice of Informal Patent Application (PTO-152)
- 20) Other: \_\_\_\_\_

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***Detailed Action***

1. Receipt of completion of filing requirements for international application entering National Stage in the U.S. designated office under 35 U.S.C.371 (Paper No. 5, 12/5/200) is acknowledged. Currently, claims 1-10 are under consideration for examination by the Examiner.

***Formal matters:***

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d), a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

***Specification***

***Objections:***

3a. The attempt to incorporate subject matter into this application by reference to Nature Medicine 1997, Nov; 3(11):1266-70 (page1, 2<sup>nd</sup> para. of the specification) or J Biol Chemistry 1998, 273 (12): 12407-12414 (IDS) is improper because the polynucleotide sequence is essential requirement of this application. A paper copy of the polynucleotide, and polypeptide sequences and a CRF need to be submitted in order to comply with the sequence rules.

3b. Recitation in page 1, 2<sup>nd</sup> para, lines 6-8 of the specification 'Further, the primary structure has almost been reported (Nature Med:., .....)' fails to imply with certainty whether that has been reported or not reported. Appropriate correction is required.

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3c. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). Therefore, the specification should contain a reference to the PCT in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph.

***Claim Rejections - 35 USC § 101***

4 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 9, and 10 are rejected under 35 USC § 101 because the claimed recitation of 'use of protein M161Ag...' in claims without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 USC § 101. See for example Ex parte Dunki, 153 USPQ 678 (Bd. App. 1967) and Clinical Products, Ltd v. Brenner, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 112-Written Description***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 6-10 recite “....a protein M161Ag or gene recombination products thereof....”. The specification does not provide a description for gene recombination products of protein M161Ag that requires use of polynucleotide sequence data for expression of the protein M161Ag, because the Applicant has not provided the sequence data.

Claims 1, 6-10 are drawn to obtaining gene recombinant products, and expressing the polypeptide products of protein M161Ag to be used as a cytokine inducer. The claimed polypeptide M161Ag can be expressed from the isolated nucleic acid encoding it. However, the isolated polynucleic acids with a definite SEQ ID No. have not been provided as per the written description requirements of 35 USC § 112-first paragraph. Applicants must convey with reasonable clarity, to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. Therefore, knowledge of the polynucleotide sequence of protein M161Ag does not allow one skilled in the art to envision and make the polypeptide M161Ag of the instant invention. Conception of the claimed invention cannot be achieved until reduction to practice has occurred, regardless of the complexity or simplicity of potential methods for expressing the protein M161Ag by using gene recombinant products. Therefore, Applicants have not provided sufficient evidence that they were in possession, at the time of filing, of the invention as it is claimed and thus the written description requirement has not been satisfied for the claims as they are recited. Applicants' attention is drawn to Guidelines for the Examination of patent Applications under 35 U.S.C. 112, first paragraph, “Written Description” requirement , Federal Register, Vol. 66, No. pages 1099-1111, Friday January, 2001.

Claims 2-5 are rejected insofar as they depend on claim 1.

***Claim Rejections - 35 USC § 112-Scope***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- 6a. Claims 1-2, and 6-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for cytokine inducers comprising a protein M161Ag, does not reasonably provide enablement for remedy or therapeutic use of M161 Ag that can induce a combination/group/list of the cytokines, namely IL-β, TNF-α , IL-6, IL-10, IL-12, and IFN-γ. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/practice the invention commensurate in scope with these claims.

Claim 2 recites the list of cytokines induced by the cytokine inducer M161Ag as IL-β, TNF-α , IL-6, IL-10, IL-12, and IFN-γ. The specification is non-enabling for this particular list of cytokines as a group to be capable of providing (a) immunomodulation that is beneficial to subject in need of cytokines termed 'cytokine deficiency'; or (b) immunological diseases that benefit from therapeutically sufficient amounts of cytokine induction. Once the cytokine inducer M161Ag is administered, the subject would synthesize all the cytokines that are part of this list namely IL-β, TNF-α , IL-6, IL-10, IL-12, and IFN-γ or which ever cytokines are in the pathway of the induction process. However, each of these cytokines has a distinct mode of action such as either anti-inflammatory or proinflammatory (as described in page 5 of the specification). The amounts of each of these cytokines induced during M161Ag administration and in what tissue determines the sum total of the beneficial/detrimental effect of these group of cytokines.

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Applicant has not provided enough guidance as to what is the outcome of such treatments in achieving an immunomodulatory response in a given real-world context. The predictability of such outcome is not based on any experience.

The Applicants claim that administration of M161Ag can be used therapeutically or to provide a remedy for immunological diseases. The state of the art approach is to administer each cytokine as required and then predict the outcomes rather than explaining the results of the unpredictable outcome. Therefore, it would require undue experimentation to determine which cytokines are needed and have desirable biological activity in a particular therapeutic modality, which cytokines should be considered as detrimental for therapy or remedy of the disease condition.

6b. Claims 6-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for cytokine inducers comprising a protein M161Ag, does not reasonably provide enablement for treatment or remedy of 'all' immunological diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/practice the invention commensurate in scope with these claims.

Claims 4, 6-10 broadly recite that cytokine inducers comprising a protein M161Ag as a remedy or therapeutic method for immunological diseases. This recitation can be read to encompass that the instant cytokine inducer is a remedy for all immunological diseases. However, the specification is non-enabling for administration of this cytokine inducer, M161Ag for immunological disease of all types with characteristics not described in the specification, because there is just minimal guidance provided for 'allergic diseases as being due to hyperimmune reaction' (page 5, 4<sup>th</sup> para, lines 4-5 of the specification), but not for any other

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specific immunological disease(s). For example, the scope of immunological diseases in general can be vast including HIV infection, and autoimmune diseases. The etiology, prognosis of the many immunological diseases is very distinct and therefore the time, dose, route of administration, end points to measure and expected treatment outcomes would be extremely diverse leading to unpredictability and undue experimentation. It would be extremely difficult to be able to use the state-of-the-art knowledge available right away to make generalizations based on the minimal guidance provided in the specification.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, is it undue (In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404). Therefore, considering the scope of the invention, state-of-the-art, predictability and guidance provided in the specification, the amount of experimentation required is undue to practice the invention as claimed.

***Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-2, 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7a. Claim 1 recites 'M161Ag' as the cytokine inducer. It is not clear as to what is the full name of this polypeptide, and if the use of 'm161ag' or 'M161Ag' is consistent. Use of acronyms can be confusing because the same acronym may be used for more than one

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molecule/protein, or use of the acronyms is also subject to change. Therefore, at least for the first time the abbreviated name of the M161Ag is used, it is necessary to write the expanded form.

7b. Claim 2 recites the list of cytokines induced by the cytokine inducer M161Ag. The list of acronyms consists of several different cytokines. At least when used for the first time it is essential to expand the full name of each of these cytokines that the acronym references.

7c. Claim 2 also recites INF- $\gamma$ . The Applicant may be referencing interferon-gamma, correctly abbreviated as IFN and not INF.

7d. Claims 9, and 10 recite "use of protein M161Ag or gene recombination products ....". It is unclear as to how to use this protein M161Ag as a cytokine inducer with the way the claim language reads without details of the process steps involved. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Therefore, recitation such as "A method of induction of cytokines comprising administration of protein M161Ag ...." would obviate this rejection.

### ***Conclusion***

8. No claims are allowed.

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***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarada C Prasad whose telephone number is 703-305-1009. The examiner can normally be reached Monday – Friday from 8.00 AM to 4.30 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sarada Prasad, Ph.D.

Examiner

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March 9, 2001

*Prema Mertz*  
PREMA MERTZ  
PRIMARY EXAMINER